05/10/2022

Review of the EFSA's bee Guidance Document

Senior Scientific Officer,
Pesticide Unit, EFSA

Trusted science for safe food

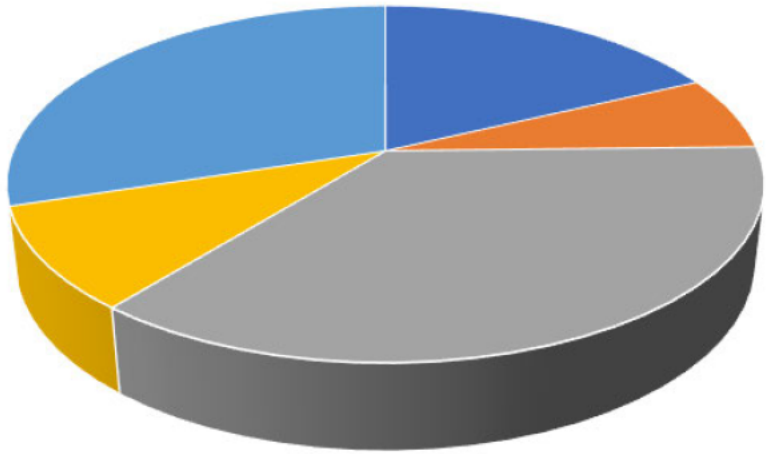
European Food Safety Authority

Execution of the ToRs of the mandate

- Co
- Co
- Re
- Re
- Re
- Re

LIVE

Link to the comments: https://open.efsa.europa.eu/consultations/a0c7U000001MVM9QAO?search=bee



- Other
- Consultant
- EFSA Registered Stakeholder
- Non-Governmental Organisation (NGO)
- Public Authority in EU Member State

BREAKING NEWS

~1500 COMMENTS ON THE DRAFT

11:13 EFSA GOT ABOUT 1500 COMMENTS FOR THEIR NEW BEE GD FROM THE PC

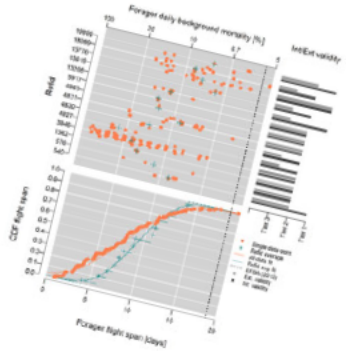
Exposure

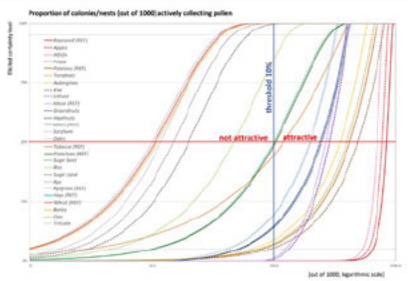
Exposure

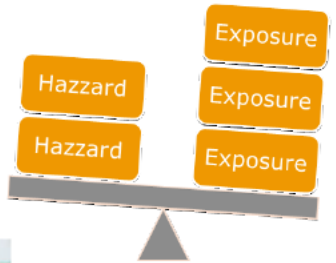
Exposure

Execution of the ToRs of the mandate

- Consider feedback from stakeholders
- Consider SPG from RM
- Review bee background mortality
- Review crop attractiveness
- Review RA methodologies
- Review requirements for higher tier







What have not been changed

- Scope

for Regulation (EC) 1107/2009 for direct effects and with the focus on chemicals

- Dust drift

progress on the draft GD on seed treatments is still awaited

Main changes from 2013

- New SPG
- Water scenarios reconsidered
- Exposure estimations updated
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- 'accumulative toxicity' (TRT) reconsidered
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Dimen-sions	Honey bees	Bumble bees	Solitary bees
Ecological Entities	Colony	Colony	Population
Attribute	Colony strength	Colony strength	Population abundance
Magnitude	≤ 10%	Undefined	Undefined
Temporal scale	Any time	Undefined	Undefined
Spatial scale	Edge of field	Edge of field	Edge of field

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- Literature and existing field studies have been analysed
  - physiological needs
  - importance of exposure via water
  - practical issues

☛ The conclusion is relevant for the context of this guidance document (including the SPG and the ExAG)

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- New exposure models
  - reparameterization of key parameters (data collection, EKE)
  - new parameters involved (Bsf, PFF, LF)
- Multiple applications considered
- Pre-flowering and during flowering applications differentiated

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- Clear list of parameters that might be refined
- Guidance/considerations for the methods of refinements provided
- Clear guidance for the 'exposure field studies'

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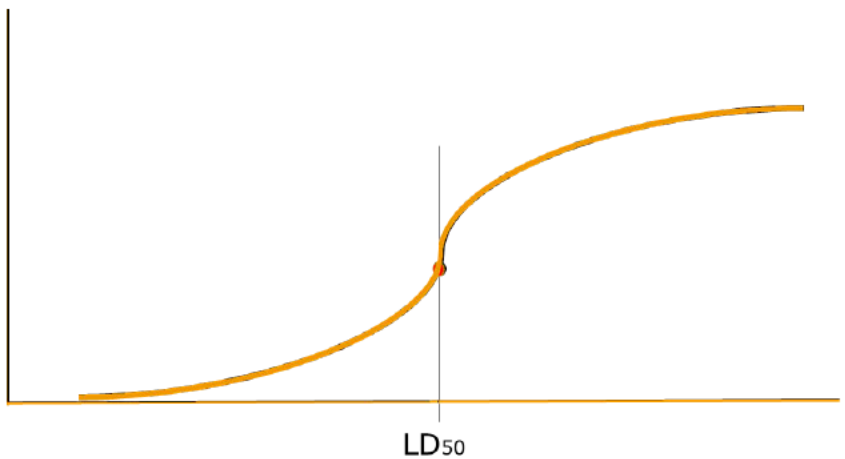
- **Full dose-response to be considered**
  - median lethal dose (LD_{50}/LDD_{50})
  - slope



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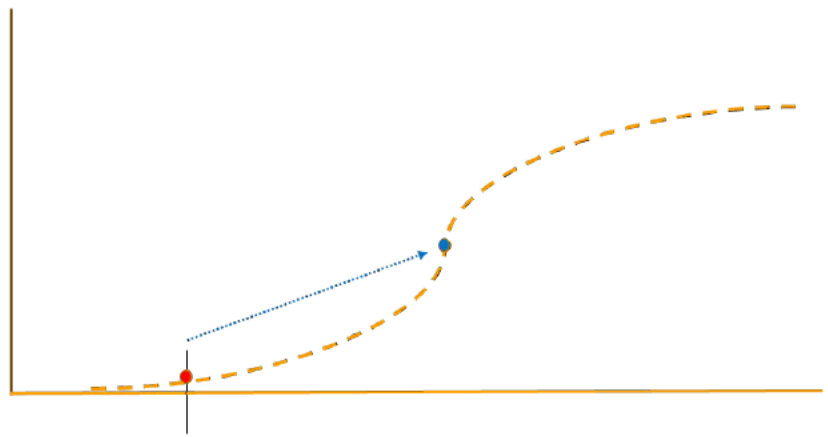
- **Worst-case slope agreed**
  - limit tests
  - technical issues with testing (e.g. solubility)



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- Separate factors to extrapolate from HBs to
  - small bw BB
  - small bw SB
- Extrapolation within the bee groups
  - *B. terrestris* to small bw BB
  - *Osmia spp*. to small bw SB

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- Starting point is the existing chronic study
- Elaborated workflow with different steps and options
- Considerations for life-long effects on
  - summer bees
  - winter bees

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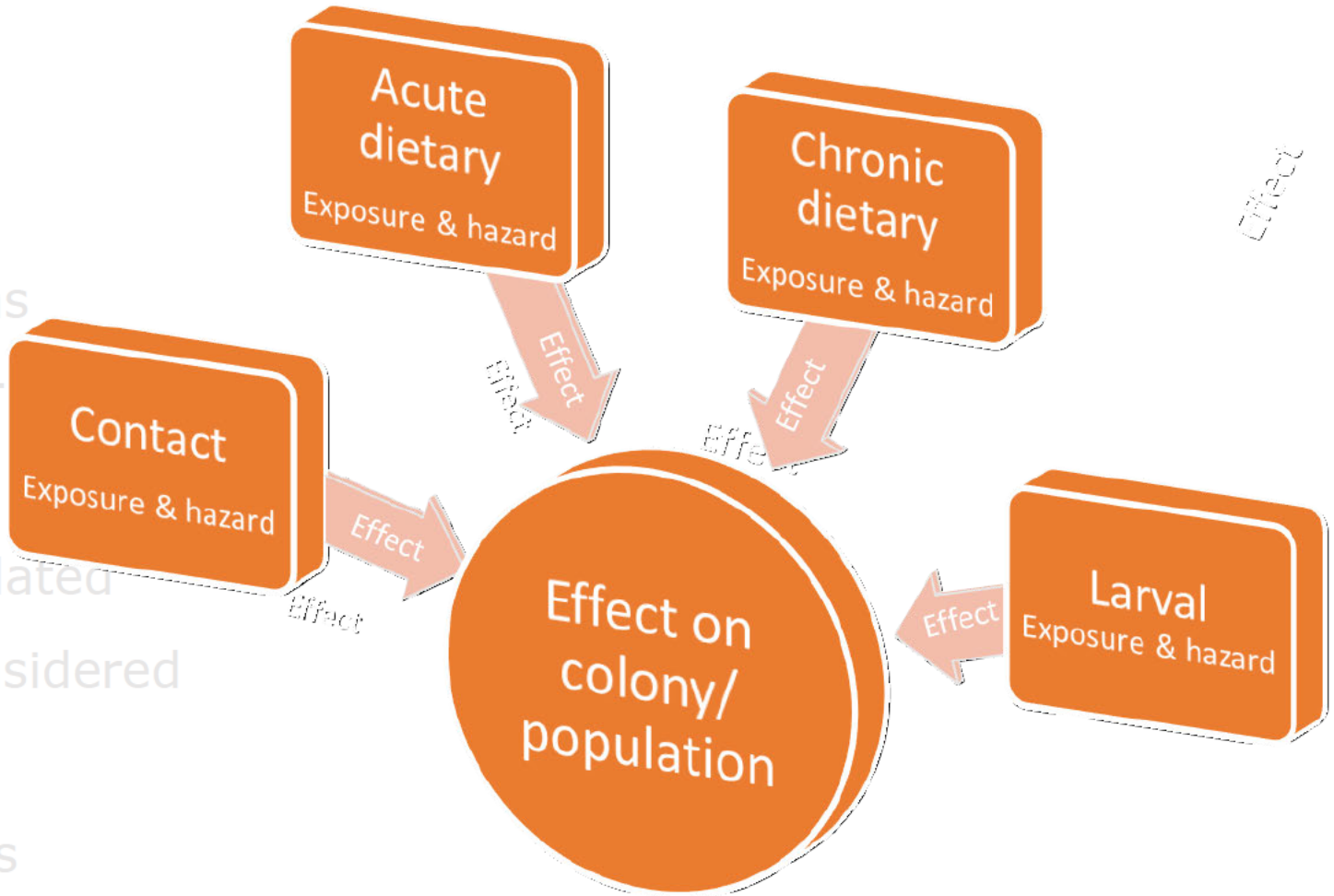

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- Elaborated workflow with different steps and options

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- Guidance/considerations for the methods (existing methods considered)
- Clear list of endpoints
  - linked to the SPG as far as it was defined

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Difference test

$p > \alpha$: effect not proven

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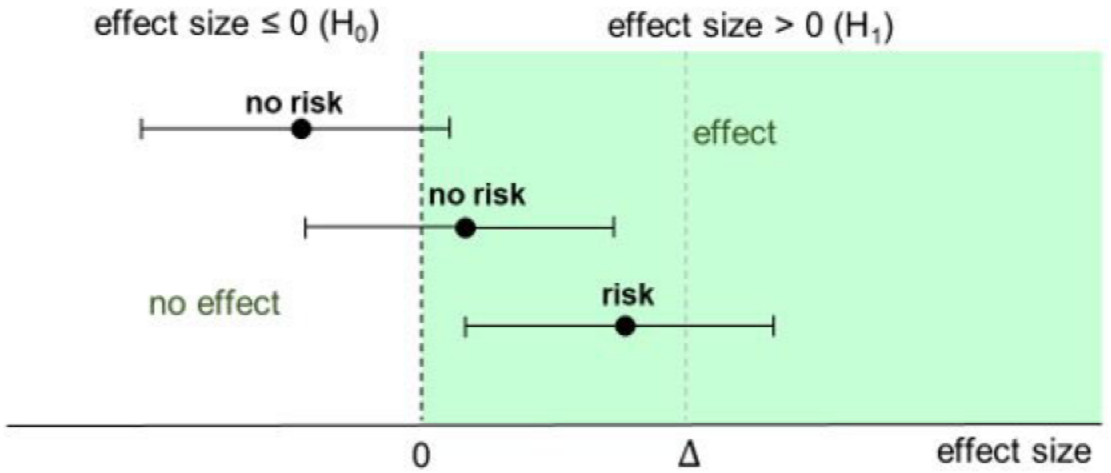
$p < \alpha$: effect proven

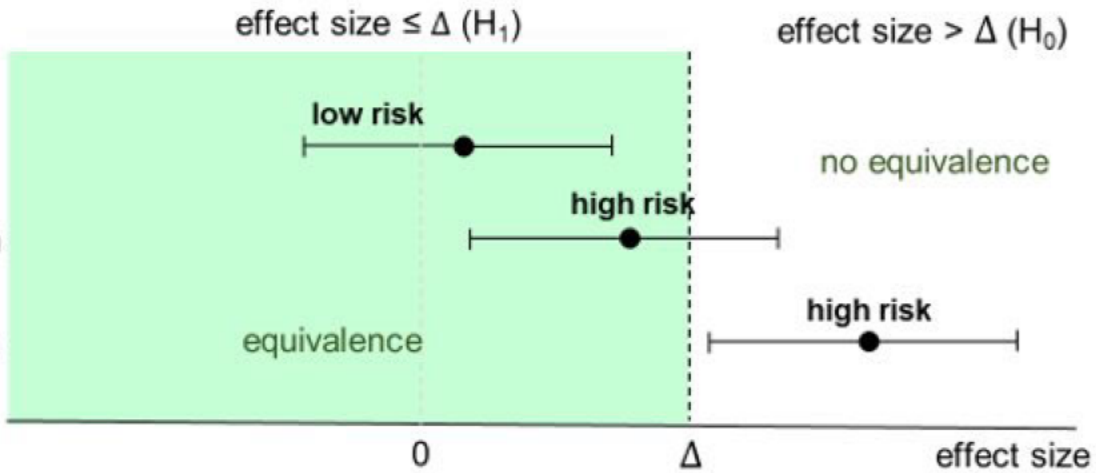


Equivalence test

$p < \alpha$: equivalence proven

$p > \alpha$: equivalence not proven

$p > \alpha$: equivalence not proven



Next steps

- Digest the comments from the PC – autumn 2022
  - Organize/structure the comments
  - Answer to the comments
  - Identify issues to be reflected/subject of change
- Review the draft – winter-spring 2023
  - WG discussions
  - Corrections/re-drafting
- Finalize drafting – spring 2023 (?)
- Issue and inform RMs – before summer 2023 (?)

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